

**UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TEXAS  
SAN ANTONIO DIVISION**

WAVE NEUROSCIENCE, INC. a Delaware Corporation,

Plaintiff,

vs.

BRAIN FREQUENCY LLC, a Texas Limited Liability Company

Defendant.

Case No. 5:23-CV-00626-XR

Honorable: Xavier Rodriguez

**PLAINTIFF'S RESPONSIVE CLAIM CONSTRUCTION BRIEF**

## TABLE OF CONTENTS

	Page
I. INTRODUCTION.....	1
II. Level of Ordinary Skill in the Art .....	1
III. Legal Standard for Claim Construction.....	3
IV. Claim Terms in Dispute.....	6
A. “[A method of] improving a physiological condition or a neuropsychiatric condition” .....	6
B. “Intrinsic Frequency” .....	9
C. “Q-Factor” .....	13
D. “Coherence Value” .....	15
E. “move an/the [intrinsic frequency...QFactor...]”/ “moving, using the magnetic field, ....[an intrinsic frequency,...QFactor...]”.....	19
F. “Control the Magnetic Field” .....	23
G. “A frequency that decreases blood flow in a lower region of the brain of the subject”/”The magnetic Field . . . decreases the blood flow of a lower region of the brain” .....	25
H. “adjusting [a setting].../[frequency]/[output].....	27
I. “One synchronized magnetic field” .....	27
J. “Close to the Head”.....	28
K. “Second” and “third” intrinsic frequency.....	30

## TABLE OF AUTHORITIES

	<b>Page(s)</b>
<b>Cases</b>	
<i>AbbVie Deutschland GmbH &amp; Co., KG v. Janssen Biotech, Inc.</i> , 759 F.3d 1285 (Fed. Cir. 2014).....	5
<i>Apple Inc. v. Motorola, Inc.</i> , 2012 WL 8123793 (N.D. Ill. Mar. 12, 2012).....	14, 15
<i>Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.</i> , 598 F.3d 1336 (Fed. Cir. 2010).....	5, 17
<i>Arterbury v. Odessa Separator, Inc.</i> , 2019 WL 570741 (E.D. Tex. Feb. 12, 2019).....	12, 22
<i>Ball Metal Bev. Container Corp. v. Crown Packaging Tech., Inc.</i> , 838 Fed. App'x 538 (Fed. Cir. 2020).....	16
<i>Bd. of Regents, The Univ. of Texas Sys. v. Ethicon, Inc.</i> , 2020 WL 3580147 (W.D. Tex. Apr. 15, 2020).....	6
<i>Biosig Instruments, Inc. v. Nautilus, Inc.</i> , 783 F.3d 1374 (Fed. Cir. 2015).....	5
<i>Butamax Advanced Biofuels LLC v. Gevo, Inc.</i> , 117 F. Supp. 3d 632 (Fed. Cir. 2015).....	16
<i>CollegeNet, Inc. v. ApplyYourself, Inc.</i> , 418 F.3d 1225 (Fed. Cir. 2005).....	4, 10
<i>Control Resources, Inc. v. Delta Electronics, Inc.</i> , 133 F. Supp. 2d 121 (D. Mass. 2001).....	4, 13, 14
<i>Datacore Software Corp. v. Scale Computing, Inc.</i> , 2023 WL 5207928 (D. Del. Aug. 14, 2023).....	5
<i>Datamize LLC v. Plumtree Software, Inc.</i> , 417 F.3d 1342 (Fed. Cir. 2005).....	4, 5
<i>Digital Biometrics, Inc. v. Identix, Inc.</i> , 149 F.3d 1335 (Fed. Cir. 1998).....	3
<i>Enzo Life Sciences, Inc. v. Digene Corp.</i> , 305 F.Supp.2d 400 (D. Del. 2004).....	18

<i>Eon CorpIP Holdings LLC v. Aruba Networks Inc.</i> , 62 F.Supp.3d 942 (N.D. Cal. 2014) .....	29
<i>Grace Instrument Industries, LLC v. Chandler Instruments Company, LLC</i> , 57 F.4th 1001 (Fed. Cir. 2023) .....	22
<i>Hockerson-Halberstadt, Inc. v. Converse Inc.</i> , 183 F.3d 1369 (Fed. Cir. 1999).....	26
<i>i2 Techs., Inc. v. Oracle Corp.</i> , No. 6:09-cv-194, 2011 WL 209692 (E.D. Tex. Jan. 21, 2011) .....	3
<i>Invitrogen Corp. v. Biocrest Mfg., L.P.</i> , 327 F.3d 1364 (Fed. Cir. 2003).....	8
<i>Kara Tech., Inc. v. Stamps.com, Inc.</i> , 582 F.3d 1341 (Fed. Cir. 2009).....	4
<i>Markman v. Westview Instruments, Inc.</i> , 52 F.3d 967 (Fed. Cir. 1995) .....	3
<i>Nautilus, Inc. v. Biosig Instruments, Inc.</i> , 572 U.S. 898 (2014) .....	4, 8
<i>Nevro Corp. v. Bos. Sci. Corp.</i> , 955 F.3d 35 (Fed. Cir. 2020) .....	4
<i>Niazi Licensing Corporation v. St. Jude Medical S.C., Inc.</i> , 30 F.4th 1339 (Fed. Cir. 2022) .....	18
<i>One-E-Way, Inc. v. Int'l Trade Comm'n</i> , 859 F.3d 1059 (Fed. Cir. 2017).....	4
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005).....	3
<i>PPG Industries, Inc. v. Guardian Industries Corp.</i> , 75 F.3d 1558 (Fed. Cir. 1996).....	6
<i>Radiancy, Inc. v. Viatek Consumer Prod. Grp., Inc.</i> , 138 F. Supp. 3d 303 (S.D.N.Y. 2014), as amended (Apr. 1, 2014).....	6
<i>Sonix Tech. Co., Ltd. v. Publications Int'l, Ltd.</i> , 844 F.3d 1380 (Fed. Cir. 2017).....	5
<i>Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.</i> , 655 F.3d 1364 (Fed. Cir. 2011).....	5

<i>U.S. Silica Co. v. Amberger Kaolinwerke Eduard Kick GmbH, No. 2:20-CV-00298- JRG.....</i>	8
<i>Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576 (Fed. Cir. 1996).....</i>	3
<i>Wyeth and Cordis Corp. v. Abbott Laboratories, 720 F.3d 1380 (Fed. Cir. 2013).....</i>	6, 25
<b>Statutes</b>	
35 U.S.C. § 112.....	6
35 U.S.C. § 282(b)(3)(A) .....	6

## I. INTRODUCTION

Defendant's proposed constructions, both alternatively and collectively, lack support in the intrinsic evidence, run directly counter thereto, improperly limit the proposed construction to a single disclosed embodiment from the Asserted Patents, and are simply not helpful to the Court or jury. Similarly, Defendant's assertions as to invalidity (regardless of the specific basis relied upon) suffer a similar fate because they either intentionally ignore or misstate the disclosure contained within the Asserted Patents, misapply applicable law, and/or fail to meet the requisite legal standard in order to prevail.

Moreover, as will be explained in a forthcoming Motion to Strike, Dr. Dempsey's Declaration in Support of Defendant's Opening Claim Construction Brief cannot save Defendant's proposed constructions. Foremost, because Dr. Dempsey does not qualify as a POSITA, and because his opinions are conclusory and/or lack the requisite support of either the intrinsic evidence or extrinsic evidence, as applicable. Consequently, both individually and collectively, Defendant's arguments should be rejected in favor of Wave's proposed constructions, which are fully supported by the intrinsic and extrinsic evidence, as applicable, comply with the governing legal principles, and are likely to assist the jury.

## II. LEVEL OF ORDINARY SKILL IN THE ART

Contrary to Defendant's representations, a POSITA at the time of the Asserted Patents would not be a person merely having a "graduate degree in mental health, neuroscience, or a related field with substantially similar courses, and 3-4 years of work experience". *See* Dkt. 34 at \*4. A graduate degree in "mental health" and other "related field[s]" would *not* provide the training and education necessary to be a POSITA for the Asserted Patents. Bikson Dec. ¶ 17. Importantly, neither Defendant nor its expert, Dr. Dempsey, provide any explanation why such education or

background would qualify a person as a POSITA for the Asserted Patents.

As explained by Plaintiff's expert, Dr. Marom Bikson, a POSITA requires "knowledge and familiarity with electrophysiology and signal processing", obtained by a background in "Electrical Engineering or Biomedical Engineering or similar discipline with classes or experience directed to electrophysiology and signal processing and TMS". Dkt. 32 at \*5. These patents are engineering based and used in the context of treatment for mental health disorders. Bikson Dec. ¶ 14. A background and training in mental health will not provide the necessary background and understanding for the technology disclosed and claimed in these patents.

Nor is "having advanced training and experience in use of either EEG or TMS technology" sufficient. *See* Dkt. 34 at \*4 (emphasis added). As Defendant admits, the Asserted Patents are directed "towards improving neurological conditions using what is known as Transcranial Magnetic Stimulation ("TMS") or ("rTMS")". *Id.* at \*1. Defendant also understands that TMS technology, not EEG technology, is central to the Asserted Patents. *See also* Bikson Dec. ¶ 15. Moreover, training and experience in "EEG" technology would not qualify a POSITA to opine regarding the '111 Patent, which is specifically directed to "non-EEG biological metrics". *See* Dkt. 029-2, '111 Patent, at 7:57-58; Bikson Dec. ¶ 16. Thus, experience and training in EEG technology is similarly insufficient to qualify as a POSITA for the Asserted Patents.

As detailed in Wave's forthcoming<sup>1</sup> Motion to Strike the Expert Declaration of Dr. Jared Dempsey, Dr. Dempsey appears to have no experience or training regarding EEG or TMS treatments. Thus, Defendant's definition for a POSITA appears to be an ill-fated attempt to qualify its own expert as a POSITA. Moreover, Dr. Dempsey is clearly biased in favor of Defendant. His

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<sup>1</sup> Wave delayed filing the Motion to Strike at the request of Defendant who refused to confirm whether it would oppose a motion designed to exclude its expert's entire testimony by May 31, 2024 absent further conference.

employer, Trac9, has a business relationship with the Wellness Ranch, a former Defendant in this case and an associated business owned by Defendant. *See Tache Dec.* ¶¶ 2-7.

### **III. LEGAL STANDARD FOR CLAIM CONSTRUCTION<sup>2</sup>**

The purpose of claim construction is for the Court to define the proper scope of the invention and to discern the meaning of the claim language the jury might otherwise misunderstand in the context of the patent and file history. *See, e.g., i2 Techs., Inc. v. Oracle Corp.*, No. 6:09-cv-194, 2011 WL 209692, \*4 (E.D. Tex. Jan. 21, 2011). Terms or phrases in a patent claim should be given “their ordinary and customary meaning,” which is “the meaning that the term would have to [POSITA] in question at the time of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). Where the plain and ordinary meaning of a claim term is understandable and consistent with the specification, the term requires no construction. *See, e.g., i2 Techs., Inc.*, 2011 WL 209692, at \*4.

However, if such meaning is not readily apparent, the Court *must* look to the intrinsic evidence: (1) the patent claims; (2) the patent specification; and (3) the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995). In many patent infringement lawsuits, “an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). However, “if after consideration of the intrinsic evidence there remains doubt as to the exact meaning of the claim terms, consideration of extrinsic evidence may be necessary to determine the proper construction.” *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344 (Fed. Cir. 1998). Extrinsic evidence should always be “considered in the context of the intrinsic evidence.” *Phillips*, 415 F.3d at 1319.

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<sup>2</sup> A broad summary of the relevant legal standard is included with Plaintiff’s Opening Claim Construction Brief. *See* Dkt. 32 at \*6-10. Plaintiff incorporates that summary into this brief.

The claims, *not* specification embodiments, define the scope of patent protection and the *patentee is entitled to the full scope of his claims*, without being limited to only the embodiments in the specification. *See Kara Tech., Inc. v. Stamps.com, Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009). Unless there is a clear intention by the Applicant, the court “will not at any time import limitations from the specification into the claims.” *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005). If a claim term is technical, the court may provide a construction for the jury to help the jury understand complicated technical concepts. *See Control Resources, Inc. v. Delta Electronics, Inc.*, 133 F. Supp. 2d 121, 127, (D. Mass. 2001).

A patent is only invalid for indefiniteness “if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014) (emphasis added). A classic example of indefiniteness is the term “aesthetically pleasing,” which the Federal Circuit in *Datamize LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1345 (Fed. Cir. 2005), found was “purely subjective,” rendering claims drawn to the “look and feel” of an interface screen invalid. While purely subjective terms are indefinite, “[t]erms of degree are not ‘inherently indefinite,’ and ‘absolute or mathematical precision is not required.’” *One-E-Way, Inc. v. Int'l Trade Comm'n*, 859 F.3d 1059, 1068 (Fed. Cir. 2017). Instead, it requires only that “a patent . . . be precise enough to afford clear notice of what is claimed, . . . while recognizing that absolute precision is unattainable.” *Nautilus*, 572 U.S. at 909–10.

Simply because a term is susceptible to more than one meaning does not make it indefinite: “Such a test would render nearly every claim term indefinite so long as a party could manufacture a plausible construction.” *Nevro Corp. v. Bos. Sci. Corp.*, 955 F.3d 35, 41 (Fed. Cir. 2020). To a POSITA, reasonable certainty in claim scope may allow for both a subjective and objective

determination. *See Datamize*, 417 F.3d at 1350. “[T]he degree of precision necessary for adequate claims is a function of the nature of the subject matter.” *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1382 (Fed. Cir. 2015); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1373-74 (Fed. Cir. 2011) (finding term “controlled environment” was not indefinite despite the lack of specific numerical parameters for measuring humidity, temperature, and airflow because “a person of skill in the art of tobacco curing would possess adequate understanding to manipulate these variables to create a controlled environment” based on industry standards).

Factors in favor of finding a claim term or phrase to be definite include whether the Patent Examiner had difficulty in applying or analyzing the term during prosecution. *See Sonix Tech. Co., Ltd. v. Publications Int'l, Ltd.*, 844 F.3d 1380, 1378-81 (Fed. Cir. 2017). “In some cases . . . resolution of indefiniteness as part of claim construction may be either impossible or inadvisable. Where, for example, there is a subsidiary factual issue, and the record reveals a genuine dispute of material fact, resolution may have to await further evidentiary development.” *Datacore Software Corp. v. Scale Computing, Inc.*, 2023 WL 5207928, at \*5 (D. Del. Aug. 14, 2023).

A patent may also be invalid if it fails to provide a sufficient written description. The written description “must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351–52 (Fed. Cir. 2010) (internal citations and quotations removed). *See also Abbvie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1298, 1300 (Fed. Cir. 2014) (“The essence of the written description requirement is that a patent applicant, as part of the bargain with the public, must describe his or her invention so that the

public will know what it is and that he or she has truly made the claimed invention.”).

Likewise, a patent may be deemed invalid if it is not enabled. “Claims are not enabled when, at the effective filing date of the patent, one of ordinary skill in the art could not practice their full scope without undue experimentation.” *Wyeth and Cordis Corp. v. Abbott Laboratories*, 720 F.3d 1380, 1384 (Fed. Cir. 2013). “The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation must not be unduly extensive.” *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996) (internal quotations removed). The specification as a whole must be considered in determining whether a claim is enabled. *Application of Johnson*, 558 F.2d 1008, 1017 (C.C.P.A. 1977).<sup>3</sup>

“A patent shall be presumed valid . . . The party asserting invalidity must prove by clear and convincing evidence the patent is invalid.” *Bd. of Regents, The Univ. of Texas Sys. v. Ethicon, Inc.*, 2020 WL 3580147, at \*2 (W.D. Tex. Apr. 15, 2020) (quoting 35 U.S.C. § 282 and citing *Microsoft Corp. v. I4I Ltd. Partnership*, 564 U.S. 91, 95 (2011)).

#### **IV. CLAIM TERMS IN DISPUTE**

Wave will address claim term numbers 12-13 and 17-25 as listed in the Amended Joint Claim Construction Chart (Dkt. 31 at \*6-18) in this Responsive Claim Construction Brief.<sup>4</sup>

##### **A. “[A method of] improving a physiological condition or a neuropsychiatric condition”<sup>5</sup>**

No.	Claim Term/Phrase	Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
10	[A method of] improving a physiological condition or a neuropsychiatric condition	to make or become better [the medical conditions in the claim]	Indefinite and unpatentable subject matter.

<sup>3</sup> While best mode remains a requirement (see 35 U.S.C. § 112), it “may no longer be used as a defense in a patent litigation action.” *Radiancy, Inc. v. Viatek Consumer Prod. Grp., Inc.*, 138 F. Supp. 3d 303, 318 (S.D.N.Y. 2014), as amended (Apr. 1, 2014); 35 U.S.C. § 282(b)(3)(A).

<sup>4</sup>Claims 12-13 and 17-25 include the 2 terms that both Parties agree should be construed, and 9 terms that only Defendant desires to be construed.

<sup>5</sup> For ease, Wave addresses the claim terms in the same order as in Defendant’s Opening Claim Construction Brief, without admitting or otherwise agreeing to their order of importance.

No.	Claim Term/Phrase	Plaintiff's Proposed Construction	Defendant's Proposed Construction
	'111 Patent, Claim 1		

Both Parties believe that a version of this claim term should be construed by the Court. Plaintiff proposes the construction set forth in the table above while Defendant contends that the term is indefinite and invalid. Specifically, Defendant argues that the '111 Patent “provides no guidance” as to how to quantify an improvement, a physiological condition, or a neuropsychiatric condition or “even how to determine whether any such improvement (or even change) in the condition is related to the claimed treatment.” Dkt. 34 at \*5. In support, Defendant relies on a just two paragraphs of unsupported testimony from its expert, Dr. Dempsey. *See* Dkt. 34-1 at ¶¶ 18-19. Defendant’s proposed construction ignores the relevant intrinsic evidence, examples of which are included in Plaintiff’s Opening Claim Construction Brief.<sup>6</sup> *See* Dkt. 32 at \*22-24.

Claim 1 of the '111 Patent uses the term “improving” to describe the clinical purpose of making the symptoms associated with these classes of disorders better, and clinicians know how to evaluate patient symptoms and whether they have been reduced. *See* Dkt. 32-5 ¶¶ 24-25, 27. As explained by Dr. Bikson in his declaration filed in support of Plaintiff’s Opening Claim Construction Brief (“Bikson Op. Dec.”), “improving” is used in its plain and ordinary sense of “to make or become better” the physiological and neuropsychiatric conditions.<sup>7</sup> Dkt. 32-5, Bikson Op. Dec. ¶¶ 51-54. Contrary to Defendant’s representations, the '111 Patent includes multiple disclosures and examples of using the patented invention to improve or reduce the symptoms of patients suffering from a physiological or neuropsychiatric condition. This is an objective inquiry that relies on a clinically determined baseline against which the treatment’s effectiveness in

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<sup>6</sup> Defendant does not argue that the “physiological condition or neuropsychiatric condition” phrase is indefinite. In fact, Defendant defines the terms using the specification. *See* Dkt. 34 at \*5.

<sup>7</sup> “Improving” is also defined in extrinsic evidence, such as dictionary definitions, as “make better”. *See* Bikson Op. Dec. ¶¶ 53-54.

reducing the patient's symptoms can be reliably measured. Bikson Op. Dec. ¶ 40. Some examples of these teachings are below (with emphasis added as needed):

- “A decrease in gamma band activity may be associated with cognitive decline, such as Alzheimer's disease. rTMS in this range is used to **treat** cognitive deficits in Alzheimer's disease or other forms of dementia.” Dkt. 029-02, '111 Patent, 4:18-26; Bikson Op. Dec. ¶ 39.
- Following 3 sessions of rTMS, the patient showed a **significant reduction in pain**. The EEG pattern showed significant improvement in alpha synchronization.” Dkt. 029-02, '111 Patent, 7:21-26. *See* Bikson Op. Dec. ¶ 42.
- After 2 weeks of daily (Monday-Friday) rTMS sessions the patient became more coherent and her MMSE score improved from 14 pre-treatment to 21 post treatment.” Dkt. 029-02, '111 Patent, 7:35-43. *See* Bikson Op. Dec. ¶ 43.

Likewise, the prosecution history for the '111 Patent confirms that the Examiner did not have any difficulty in understanding the term “improving”. *See* Bikson Dec. ¶ 26. Defendant faults Plaintiff for not providing a specific method of measuring if each and every type of physiological or neuropsychiatric condition has been improved. Dkt. 34 at \*6. However, mathematical precision is not required for a claim to be definite. *See Nautilus*, 572 U.S. at 909–10. Instead, the standard requires that a claim provide sufficient detail for a POSITA to understand whether a physiological or neuropsychiatric condition has been improved. Here, a POSITA would understand that improved means to “make better” and that a condition that is “made better” would have improved symptoms of that condition, such as improved memory for an Alzheimer's patient or decreased pain for a patient struggling with pain management. Bikson Op. Dec. ¶¶ 42-3. This is consistent with both case law holding that similar terms are definite and Defendant's own use and understanding of the “improving” term. *See Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1369 (Fed. Cir. 2003) (affirming construction of term “**improved** competence” as “generally increased” without any specific numerical limitation); *U.S. Silica Co. v. Amberger Kaolinwerke Eduard Kick GmbH*, No. 2:20-CV-00298- JRG, p. 22 (E.D. Tex. Nov. 19, 2021) (“**improves**

adherence” not indefinite as “a skilled artisan would understand that improvement to be relative to the adherence of the particles to the asphalt layer without any treatment”); Dkt. 32-3.

Even Dr. Dempsey understands the concept of “improved”, explaining on Trac9’s website and in podcasts that “[i]mproving clinical outcomes is dependent on feedback-informed care models”. *See Tache Dec. ¶ 9. See also id. ¶ 10* (title of podcast “[i]mproved outcomes through feedback-informed clinical care with Jared Dempsey”); *id. ¶ 8* (describing product developed by Trac9 as “GRS was created to provide a comprehensive benchmark in total improvement throughout the course of treatment.”). *See also Bikson Dec. ¶¶ 28-36* (noting the same and that Defendant’s expert and website uses “improves”). Defendant’s indefiniteness assertion fails as it runs directly contrary to the intrinsic evidence (both in the ’111 Patent itself and in the Examiner’s actions during prosecution thereof), and lacks any evidence, let alone clear and convincing evidence, establishing that improving is indefinite. Consequently, this Court should adopt Wave’s proposed construction and deny Defendant’s request that this claim term be found indefinite.

## B. “Intrinsic Frequency”

No.	Claim Term/Phrase	Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
14	Intrinsic frequency ’490 Patent, Claim 1 ’408 Patent, Claims 1-2, 12, 20 ’111 Patent, Claims 3, 7 ’737 Patent, Claims 1-2, 4	frequency selected to which treatment is to be applied	the frequency ( $f_0$ ) at which peak signal power in the specified band (Emax) is located  For ’111 Patent: Indefinite & Invalid: Not enabled/lacking written description

The second term that requires construction is “intrinsic frequency”. Wave proposes a construction supported by intrinsic evidence and using colloquial and easily understood language. Conversely, Defendant’s proposed construction violates fundamental tenants of claim construction and uses language sure to confuse to the jury.

Defendant represents that its proposed construction (“the frequency ( $f_0$ ) at which peak signal power in the specified band (Emax) is located”) comes directly and verbatim from the specification. *See Dkt. 34 at \*7; Dkt. 34-1, Dempsey Dec.* ¶ 21. Defendant’s proposed construction is not a direct quote, but is an amalgamation of multiple embodiments disclosed within the patents. *See ’490 Patent, ’408 Patent, and ’737 Patent Figure 12 and Example 6.* Specifically, Defendant, relies on a description of Figure 12 directed to *Q-Factor* (a separate and distinct option for treating patients in the ’490, ’408, and ’737 Patents) and Example 6 (directed to “mean peak” frequency) instead of relying on the many disclosures of “intrinsic frequency” found in the ’490 Patent, ’408 Patent, and ’737 Patents as the basis for its proposed construction. *See Dkt. 34 at \*7-8, \*10-12. See Bikson Dec.* ¶ 52. Because Defendant’s proposed construction runs counter to the intrinsic evidence in the Asserted Patents it should not be adopted.

Defendant’s proposed construction also violates a fundamental tenant of claim construction. Absent a clearly expressed intention by Wave to import a limitation from the specification into the claims, the Court will not import such a limitation into the claims. *See CollegeNet*, 418 F.3d at 1231; *Liebel-Flarsheim*, 358 F.3d at 906. Because Defendant makes no argument, nor can it, that Wave intended to import any limitation regarding intrinsic frequency from either Figure 12 or Example 6 into the claims, its construction cannot be adopted.

Defendant also falsely argues that the “term intrinsic frequency is not a term of art and has no ordinary meaning”. Dkt. 34 at \*7. However, a Google Scholar search shows that “intrinsic frequency” and “TMS” are commonly used together in the same manner proposed in Wave’s construction (Bikson Dec. ¶¶ 46, 56); confirming its common use and understanding in the art.

Defendant’s efforts to characterize Wave’s proposed construction of “intrinsic frequency” as “non-sensical” are equally unavailing. *See Dkt. 34 at \*8.* Defendant claims that Wave’s

proposed construction of “intrinsic frequency” will allow Wave to “rewrite the claim term to essentially mean whatever frequency it deems selectable”. In support, Defendant inserts Wave’s construction inside Claim 2 of the ’408 Patent. For ease, Wave provides the original language of Claim 2 against the comparison used by Defendant in its brief below:

'408 Patent Claim 2 Language	Defendant’s Language – Dkt. 34 at *9
“moving at least one of: an intrinsic frequency of a brain of the subject within a specified EEG band toward a <i>pre-selected intrinsic frequency</i> within the same specified EEG band”	“moving at least one <sup>8</sup> [frequency selected to which treatment is to be applied]...toward a <i>pre-selected</i> [frequency selected to which treatment is to be applied].”

However, in so arguing, Defendant ignores that the claim term “pre-selected intrinsic frequency” is the subject of a *different agreed* claim construction: “[a] targeted intrinsic frequency chosen before treatment”. *See* Dkt. 31 at \*5. This construction of “pre-selected intrinsic frequency” is binding. Had Defendant used these proper constructions, the language would read as follows:

'408 Patent Claim 2 Language	Corrected Language (without shortening)
“moving at least one of: an intrinsic frequency of a brain of the subject within a specified EEG band toward a pre-selected intrinsic frequency within the same specified EEG band”	“moving at least one of: a[] [frequency selected to which treatment is to be applied] of a brain of the subject within a specified EEG band toward [a targeted intrinsic frequency chosen before treatment] within the same specified EEG band.”

When correctly applied, Wave’s construction is consistent with the intrinsic evidence, which discloses both the patient’s own internal frequency in their brain to which the TMS treatment is applied and a pre-selected or targeted intrinsic frequency, i.e. the goal or desired result of the TMS treatment. *See* Bikson Dec. ¶¶ 41-44, 53. The following examples of intrinsic support from the

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<sup>8</sup> Unsurprisingly, Defendant’s shortened language from the claim term is misleading in other ways. For example, the shortened language as presented by Defendant implies that the claim covers moving at least one of multiple intrinsic frequencies. However, as written, the “at least one of” language refers to the two options for treatment, i.e. moving an intrinsic frequency *or* a Q-Factor.

subject specifications and prosecution histories are illustrative:

- “In another aspect are devices comprising a means for applying a magnetic field to a head of a subject; whereby the means for applying the magnetic field is capable of **influencing an intrinsic frequency** of a brain of the subject within a specified EGG band.” Dkt. 29-3, ’408 Patent at 7:12-16; Bikson Op. Dec. ¶ 63.
- “Further, Claim 2 of the present invention recites adjusting output of a magnetic field and influencing the subject's **intrinsic frequency** in a specified EEG band toward a pre-selected intrinsic frequency of **the same** EEG band. On the other hand, Katz's only intention and goal is to move a subject **from a current brain state into a desired brain state**. Since the brain states correlate to separate EEG bands in Katz (i.e. from relaxed in the alpha band to sleep in the delta or theta band), **Katz' methods and devices move the brain waves from one band to another.**” ’408 Prosecution History at \*800 (September 10, 2012 Amendment in Response to Final Office Action, p. 8) (italics in original). *See also* Bikson Op. Dec. ¶ 78.
- “In regards to claims 1 and 2, the prior art of record does not teach or suggest a method as claimed by Applicant, that includes the step of moving at least one of an **intrinsic frequency** of a specified EEG band of the subject toward a pre-selected intrinsic frequency of the specified EEG band and a Q-factor of an intrinsic frequency within a specified EEG band of the subject toward a pre-selected Q-factor using said magnetic field.” ’737 Prosecution History at \*1508 (March 25, 2014, Final Office Action, p. 5). *See also* Bikson Op. Dec. ¶ 79.

Wave’s construction is, thus, not “illogical” as Defendant proposes. Rather, it is Defendant’s construction that both violates basic patent law (i.e. that each party must use the claim constructions entered in a case) (*see Arterbury v. Odessa Separator, Inc.*, 2019 WL 570741, at \*1 (E.D. Tex. Feb. 12, 2019)) and is at odds with the intrinsic evidence.

Defendant’s other challenge to Wave’s proposed construction also fails. Defendant argues that Wave’s construction of “intrinsic frequency” conflicts with use of a “specified EEG frequency” in Claim 1 of the ’408 Patent. Dkt. 34 at \*9. However, “specified EEG frequency” in Claim 1 of the ’408 Patent is used in relation to *EEG Phase*. Unlike intrinsic frequency, Q-Factor, and coherence value; each analyzed in the frequency domain and focus on a frequency measurement, *EEG Phase* is a comparison of the timing of two waveforms, measured in these patents in the time domain. Bikson Dec. ¶¶ 54-55. To analyze the measurements in the time domain, the frequency must stay constant. *Id.* ¶ 55. Thus, the “specified EEG frequency” is the

selected frequency at which the waveform timing is analyzed. This is an entirely *different* concept than “intrinsic frequency”. Thus, the terms and Wave’s constructions are not inconsistent.<sup>9</sup>

Defendant’s argument as to “intrinsic frequency” relative to the ’111 Patent is equally flawed. Defendant argues that the ’111 Patent refers to the intrinsic frequency as a range while the claims refer to it as a single frequency in a given band.” Dkt. 34 at \*10. This is incorrect. Defendant’s use of the quoted language from the specification is taken out of context. *See* Bikson Dec. ¶ 51. Read in proper context, the quoted language from the specification merely points out the ranges that the intrinsic frequency may be selected from rather than referring to the intrinsic frequency as a “range” as Defendant claims. *Compare* Dkt. 34 at \*10 with Bikson Dec. ¶¶ 50-51. Wave’s proposed construction of “intrinsic frequency” is supported by and consistent with the intrinsic evidence of the Asserted Patents and provides guidance as to what “intrinsic frequency” means. *See also* Bikson Dec. ¶¶ 45, 47-49. As such, Wave’s construction should be adopted and Defendant’s invalidity allegations should be rejected.

### C. “Q-Factor”

No.	Claim Term/Phrase	Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
17	Q-Factor ’490 Patent, Claim 1 ’408 Patent, Claims 1-2, 12, 20 ’737 Patent, Claims 1-2, 4	Plain and ordinary meaning, namely where the Q-factor is the ratio of the intrinsic frequency relative to the frequency bandwidth at half peak energy <sup>10</sup>	Ratio of $f_0 / \Delta f$ , where $f_0$ is the intrinsic frequency and $\Delta f$ is the frequency bandwidth for which the energy is above one-half the peak energy in the specified band

Defendant’s proposed construction and supporting arguments for the claim term “Q-

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<sup>9</sup> Unlike Wave’s proposed construction that uses plain language, easily understood by the jury, Defendant’s proposed construction also contains technical terms that are not understandable to the jury. *See Control Resources*, 133 F. Supp. 2d at 127.

<sup>10</sup> Notably, Defendant failed to use the plain and ordinary meaning construction for Q-Factor proposed by Wave in the Amended Joint Claim Construction Chart. *See* Dkt. 31 at \*10-11.

Factor” suffer from many of the same errors as with the claim term “intrinsic frequency”. Again, Defendant claims that “Q-Factor” is not a term of art and has no meaning in the relevant field. *See* Dkt. 34 at \*10-11. Defendant’s assertion relies exclusively on conclusory and unsupported statements contained within Dr. Dempsey’s declaration. *See* Dkt. 34-1 ¶ 26. However, like “intrinsic frequency”, a search of Google Scholar shows that Q-Factor is a well-known concept in the art. *See* Bikson Dec. ¶ 74. For this reason alone, Defendant’s proposed construction and argument as to indefiniteness should be rejected.

Defendant’s proposed construction of “Q-Factor” is again improperly based on a specific embodiment disclosed in the subject patents. As noted above, with respect to the claim term “intrinsic frequency,” this is improper. *See supra* at \*10. Defendant again inaccurately represents that its proposed construction is taken verbatim from the patent specification. Specifically, Defendant’s proposed construction includes “ $\Delta f$  is the frequency bandwidth for which the energy is above one-half the peak energy in the specified band”. However, “in the specified band” is not used in conjunction with  $\Delta f$  in the cited language from the specification. Instead, “in the specified band” is used in conjunction with the prior phrase “ $f_0$  is the intrinsic frequency”. *See* Dkt. 029-04 at 22:24-25; Bikson Dec. ¶¶ 75-76. Defendant does not explain why it made this change and fails to provide any support justifying its inclusion in its proposed construction.

Even if Defendant’s inaccurate quotation from the specification to create its proposed claim construction for “Q-Factor” was somehow warranted, the proposed construction is not helpful to the jury. A key goal of claim construction is to help the jury understand complicated technical concepts. The law explains that the resulting construction “must result in a phraseology that can be taught to a jury of lay people . . . [in] plain English so that a jury will understand.” *Control Resources*, 133 F. Supp. 2d at 127. *See also Apple Inc. v. Motorola, Inc.*, 2012 WL 8123793 at \*1

(N.D. Ill. Mar. 12, 2012) (instructing parties that their proposed Claim constructions had to be “in ordinary English intelligible to persons having no scientific or technical background”). While Wave believes the explanation of Q-Factor is best left to the experts, its construction uses plain English and no mathematical formulas consistent with the majority of uses of Q-Factor in the patents. Bikson Dec. ¶¶ 60-73. By contrast, Defendant’s proposed construction uses technical terms such as “ $\Delta f$ ” and “ $f_0$ ” that would not be readily understood by a jury because such terms are not terms not used in “everyday parlance”. Bikson Dec. ¶¶ 77-78. For all these reasons, the Court should adopt Waves’ rather Defendant’s proposed construction of “Q-Factor”.

#### D. “Coherence Value”

No.	Claim Term/Phrase	Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
18	Coherence value  ’490 Patent, Claim 1 ’408 Patent Claims 1, 12, 20	Not indefinite or invalid.  Plain and ordinary meaning namely a measure of similarity between two or more signals over time.	Indefinite and Invalid: Not enabled / lacking written Description or in the alternative: “The difference between the frequency and phase of two waves.”

Defendant argues that “coherence value” would not be understood by a POSITA, while at the same time admitting that the term “coherence” has been and continues to be used in mathematics for decades. *See* Bikson Dec. ¶¶ 81, 96. Defendant also admits that the term “value” in this context means a number that is the result of a calculation; in this case the coherence calculation. *See id.* Despite such contradiction, Defendant argues that “coherence value” is invalid because it is indefinite, it lacks a sufficient written description, and because it is not enabled. Each of Defendant’s arguments fails in turn as detailed below.

According to Defendant, “coherence value” is indefinite because “it is an improperly claimed term of degree and/or measurement” and because the ’490 and ’408 Patents fail to disclose what measure to use to calculate a coherence value. Defendant over simplifies and improperly

states the correct legal standard in making its argument. The law states that “a claim may be invalid as indefinite when (1) different known methods exist for calculating a claimed parameter, (2) nothing in the record suggests using one method in particular, and (3) application of the different methods result in materially different outcomes for the claim's scope such that a product or method may infringe the claim under one method but not infringe when employing another method.” *Ball Metal Bev. Container Corp. v. Crown Packaging Tech., Inc.*, 838 Fed. App'x 538, 542 (Fed. Cir. 2020). Defendant fails to present arguments addressing all three requirements of this standard.

Rather than present any argument in support of its assertion that the claim term is indefinite, Defendant, in the context of its argument that the subject claim term is invalid based upon a lack of written description, claims that “there are many variations of calculating coherence generally that can yield very different results” and cites four options from its expert in support. Dkt. 34 at \*14; Dkt. 34-1 ¶ 31. Even if Defendant also intended this argument to apply to its assertion of indefiniteness, Dr. Dempsey provides no meaningful explanation of the alleged four options or explains how they would result in materially different outcomes if used by a POSITA; as is required to prevail on an indefiniteness argument. *See Butamax Advanced Biofuels LLC v. Gevo, Inc.*, 117 F. Supp. 3d 632, 640-41 (Fed. Cir. 2015).

Notably, as explained by Dr. Bikson, option 2 (i.e. Phase-Locking Value) from Dr. Dempsey’s list of four available options that can allegedly yield very different results, is an entirely *different calculation* than coherence and uses a *fundamentally different formula*. Bikson Dec. ¶ 100. Of equal import, option 3 (i.e. wavelet coherence) and option 4 (i.e. partial coherence) from Dr. Dempsey’s list are nothing other than derivatives of option 1 (magnitude-squared coherence). *Id.* ¶ 101. Thus, only one of the four options presented by Defendant serves as a true method of calculating coherence so different results are not possible.

Dr. Bikson explains that while there are a couple ways to measure coherence, these different ways do not result in materially different outcomes. Instead, they all show whether the frequency signals taken from two different parts of a subject's brain are similar. *Id.* ¶¶ 102-03. Dr. Bikson's testimony is consistent with the intrinsic evidence in the subject patents; evidence that was entirely ignored by Defendant. *See id.* ¶¶ 82-94; Dkt. 029-07, '408 Patent Prosecution History at \*738 (Applicant (Wave) explaining that “[c]ohherence, as used in the present application, refers to how closely matched are the intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band ( e.g., how closely matched is a first intrinsic frequency of a first site in the brain of the subject within a specified EEG band to a second intrinsic frequency of a second site in the brain of the subject within the same EEG band, at least).”).<sup>11</sup> As such, this argument by Defendant fails.

Defendant also claims that “coherence value” fails to meet the written description requirement. As explained above, the “test for sufficiency [of the written description] is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad*, 598 F.3d at 1351–52. Defendant appears to make two arguments regarding this sufficiency. First, Defendant argues that the written description is insufficient because there are multiple ways to calculate coherence. Dkt. 34 at \*14. This argument fails for the reasons as detailed above. *See supra* at \*16-17. Second, Defendant argues that coherence value is not “defined or explained” in the specification. Dkt. 34 at \*14. This argument also fails as explained above. *See supra* at \*17

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<sup>11</sup> While Wave disputes that options 2-4 are different options for calculating coherence value as detailed above, even if these options are valid, Wave's disclosure during the Prosecution History suggests using the magnitude-squared coherence calculation (or a similar calculation) for the coherence value is an option for calculating coherence and consistent with Wave's prior representations since this calculation provides a numerical analysis of whether the frequencies among multiple sites in a brain are matched. *See* Bikson Dec. ¶¶ 94, 99, 106.

(defining coherence value during prosecution). Moreover, there is no requirement that a term be defined explicitly in the specification to be valid. *See Niazi Licensing Corporation v. St. Jude Medical S.C., Inc.*, 30 F.4th 1339, 1347 (Fed. Cir. 2022); *Copperhead Industrial, Inc. v. Changer & Dresser, Inc.*, 2020 Markman 429484, 2020 WL 429484, \*6-\*7 (N.D. Ala. 2020); *Enzo Life Sciences, Inc. v. Digene Corp.*, 305 F.Supp.2d 400, 404 (D. Del. 2004).

Next, Defendant argues that “coherence value” is not enabled. While its argument is unclear and intertwined with its indefiniteness argument, Defendant appears to contend that the term is not enabled because the coherence value must first be determined before a magnetic field can be used to influence the coherence value. Dkt. 34 at \*14. As explained above, a POSITA would know how to measure or “determine” the coherence value, which then can be influenced using a magnetic field. As such, Defendant’s argument as to enablement fails. If, instead, Defendant’s argument is that the magnetic field must influence the coherence value, Wave incorporates its responses to the following section regarding moving the magnetic field. *See infra* at \*19-25. Moreover, the specification of the subject patent explains, how influencing or changing a coherence value can be used in the treatment of patients. *See Bikson Dec.* ¶¶ 84-93; Dkt. 029-03, ’408 Patent 22:56-23:14. Again, Defendant’s argument as to enablement fails.

Lastly, Defendant argues that if “coherence value” is not invalid, then Defendant’s proposed construction (“[t]he difference between the frequency and phase of two waves”) should be adopted, rather than Wave’s proposed construction, because it is consistent with statements in the Prosecution History. Dkt. 34 at \*14-15. However, Defendant’s supporting citation to the Prosecution History is to the Examiner’s summary of how a prior art reference (Katz) describes “coherence value”. Bikson Dec. ¶¶ 104-05. Subsequently, the Applicant (Wave) explained what coherence value means in these patents. *Id.* ¶ 106. The Examiner never disputed Wave’s

explanation and, as such, they are adopted for purposes of intrinsic evidence. *Id.* Thus, Defendant's proposed construction is without intrinsic evidence support and must fail.

**E. “move an/the [intrinsic frequency...QFactor...]”/ “moving, using the magnetic field, ....[an intrinsic frequency,...QFactor...]”**

Defendant, again, presents a jumbled assortment of arguments, ultimately arguing that the claim terms “move/moving” are invalid because they are: (i) indefinite; (ii) lack sufficient written description; and (iii) not enabled.<sup>12</sup> At their core, Defendant's arguments appear to fall into two camps: (1) arguing that the specification fails to instruct a POSITA *how* to move an intrinsic frequency, etc... and (2) arguing that the specification fails to explain *when any or what degree of* movement occurs. In both instances, Defendant ignores language from both the specification and the claims themselves that provide clear answers to these questions.

First, the asserted claims of the '408, '490, and '737 Patent each explain that the movement of the intrinsic frequency, etc... is caused using the magnetic field. Examples of the claim language from each of these patents is excerpted below (emphasis added):

- “**move** an [intrinsic frequency/Q-Factor/coherence value/EEG phase] . . . using a **magnetic field**”. Dkt. 029-03, '408 Patent, Claim 1, 66:25-44; Bikson Dec. ¶¶ 110-12.
- “wherein the **magnetic field** is configured to **move** the [...intrinsic frequency/Q-Factor...] . . . using the **magnetic field**. Dkt. 029-04, '490 Patent, Claim 1, 85:20-27; Bikson Dec. ¶ 113.
- “wherein the **magnetic field** is configured to . . . **move** the [coherence value/EEG phase]” by applying or using two **magnetic fields**. Dkt. 029-04, '490 Patent, Claim 1, 85:20-21, 85:28-39; Bikson Dec. ¶ 113.
- “**moving**, using the **magnetic field**, an intrinsic frequency”. Dkt. 029-05, '737 Patent, Claim 2, 80:16; Bikson Dec. ¶¶ 114-15.

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<sup>12</sup> Defendant's argument that “a person could infringe this claim by taking a magnet and waiving it over one's head” is particularly confusing. Defendant's argument is grounded on ignoring the remaining elements of the claim, such as moving the patient's intrinsic frequency toward a pre-selected frequency, a step that cannot be controlled via the example presented. Bikson Dec. ¶ 147. Nor does Defendant (or Dr. Dempsey) explain how such movement would meet all the requirements of the claim, instead of just this one element, improperly taken completely out of the context of the entire claim. *Id.*

The Prosecution History of these patents further supports that the magnetic field is used to move the intrinsic frequency, etc... *See* Bikson Dec. ¶ 133; '737 Prosecution History at \*1551 ("The Examiner suggested 'amending the claim to positively recite the item that moves the intrinsic frequency of the EEG band **OR** Q-factor so that it reads -- ... moving, using the magnetic field, ... --'. . . Applicants have made the suggested amendments to claims 1 and 2 . . .").

The intrinsic evidence of the '408, '490, and '737 Patents also explain how to manipulate the magnetic field in order to move the intrinsic frequency, etc.... Specifically, the '408 Patent states that the intensity, frequency, waveform, and phase can be adjusted. *See* Bikson Dec. ¶¶ 116-35; Dkt. 029-03, '408 Patent at 31:37-45. *See also* Dkt. 029-04, '490 Patent at 48:62-49:12 (stating same); Dkt. 029-05, '737 Patent at 43:52-44:2 (stating same). Certain of the claims even contain directions on how to apply the magnetic field to achieve the change or movement:

- "move a coherence value . . . using the magnetic field wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to the head of the subject" Dkt. 029-03, '408 Patent, Claim 1, 66:31-40; '490 Patent, Claim 1, 85:28-34; Bikson Dec. ¶125-27.
- "move an EEG phase . . . using the magnetic field wherein the magnetic field comprises one or more magnetic field generators that are of the same frequency and are in-phase with each other, of the same frequency and out of phase with each other, or a combination thereof". Dkt. 029-03, '408 Patent, Claim 1, 66:41-48; Dkt. 029-04, '490 Patent, Claim 1, 85:35-39; Bikson Dec. ¶¶ 129-31.

Thus, the specifications of the '408, '490, and '737 Patents plainly explain how to manipulate the magnetic field to effect change, i.e. move the intrinsic frequency, etc.... Moreover, a POSITA would understand how to manipulate the four parameters to treat each specific patient or subject.

*See* Bikson Dec. ¶¶ 135-38. Accordingly, any concern manufactured by Defendant regarding *how* to move an intrinsic frequency, etc... is caused by Defendant's own selective review of the information contained within each of the patents.

Second, Defendant also claims that, even if the specifications and claims, explain *how* a

POSITA could move the intrinsic frequency, etc..., the specifications do not explain *when* or to *what degree* such movement occurs. However, again, Defendant ignores the relevant language in the claims themselves and the specifications that answer these questions. Each of the claims contains language wherein the intrinsic frequency, etc... is moved toward a pre-selected or targeted intrinsic frequency, etc... or in a specified manner to achieve specific results. Examples of the claim language from the claims of these patents are excerpted below (emphasis added):

- “move an [intrinsic frequency/Q-Factor/coherence value/EEG phase] . . . **toward a target** [intrinsic frequency/Q-Factor/coherence value/EEG phase] . . . using a magnetic field”. Dkt. 029-03, ’408 Patent, Claim 1, 66:25-44; Bikson Dec. ¶¶ 140-41.
- “wherein the magnetic field is configured to move the [...intrinsic frequency/Q-Factor...] **in a pre-selected direction**, up or down, . . . using the magnetic field. Dkt. 029-04, ’490 Patent, Claim 1, 85:20-27; Bikson Dec. ¶ 142.
- “wherein the magnetic field is configured to . . . move the coherence value by applying the magnetic field and a second magnetic field” that are asynchronous or synchronized to reduce or raise the coherence value, respectively. Dkt. 029-04, ’490 Patent, Claim 1, 85:20-21, 85:28-34; Bikson Dec. ¶ 113.
- “wherein the magnetic field is configured to . . . move the EEG phase” by using two magnetic fields that are either in-phase or out of phase with each other. Dkt. 029-04, ’490 Patent, Claim 1, 85:20-21, 85:35-39; Bikson Dec. ¶ 113.
- “moving, using the magnetic field, an intrinsic frequency . . . of the subject **toward a pre-selected** intrinsic frequency”. Dkt. 29-5 ’737 Patent, Claim 2, 80:16-8; Bikson Dec. ¶ 143-4.

Each of the subject specifications contains multiple examples of specific directions on how to adjust an intrinsic frequency, etc... to obtain a specific movement of the intrinsic frequency, etc... for a subject. *See* ’408 Patent 1:46-67, for example. *See also* ’408 Patent 17:39-55 (similar); ’737 Patent 6:4-22 (similar); ’737 Patent 23:7-24; ’737 Patent 24:4-21; ’490 Patent 6:8-25 (similar); ’490 Patent 31:4-22; Bikson Dec. ¶ 116. These examples include treatments for specific diseases, including PTSD, coma, and Parkinson’s Disease. *See* ’408 Patent 19:27-67 (PTSD); ’408 Patent 21:16-60 (coma); ’408 Patent 24:12-61 (Parkinson’s Disease); Bikson Dec. ¶ 118. *See also*. ’408

Prosecution History at \*736-738. Moreover, a POSITA would understand how to move the intrinsic frequency, etc... to obtain the targeted outcome dictated by the claims. Bikson Dec. ¶¶ 138-46. *See also Grace Instrument Industries, LLC v. Chandler Instruments Company, LLC*, 57 F.4th 1001, 1010 (Fed. Cir. 2023) (explaining that term “enlarged chamber” was not indefinite because the term “does not require that chamber to be *larger than* some baseline object; rather it must be *large enough* to accomplish a particular function”).).

Importantly, two of the agreed constructions adopted by the Parties support Wave’s arguments. As explained previously, the Parties adopted an agreed construction of “pre-selected [intrinsic frequency/Q-Factor/coherence value/direction]” as “a targeted [intrinsic frequency/Q-Factor/coherence value/direction] chosen before treatment”.<sup>13</sup> Dkt. 31 at \*5. Thus, Defendant understands that the claims provide for a goal or “target” for the movement of the intrinsic frequency, etc.... Additionally, the Parties also agreed to construe “toward a” as “closer to”.<sup>14</sup> *Id.* at \*4. Thus, Defendant also understands that use of the phrase “toward a” means moving the intrinsic frequency, etc... closer to the goal of the claim. Defendants even *agreed* as to constructions for “move” and “moving”, subject to its invalidity arguments. *Id.* Consequently, Defendant is estopped from asserting that the claim terms “move/moving” are invalid because they are indefinite, lack sufficient written description, and/or are not enabled based upon an argument relying on its prior agreement as to the claim terms “pre-selected [intrinsic frequency/Q-Factor/coherence value/direction]” or “toward a”. *See Arterbury*, 2019 WL 570741, at \*1.

Separately, as set forth above, Defendant’s arguments as to the claim terms

<sup>13</sup> Defendant reserved its right to continue to dispute the terms “intrinsic frequency”, “Q-Factor”, and “coherence value” subject to its agreement as to the “pre-selected” terms. *See* Dkt. 31 at \*5 n.5. Defendant made no such reservation as to the “move/moving” terms.

<sup>14</sup> Unlike with the “pre-selected” terms, Defendant made no reservation of rights as to its agreed construction of “toward a”.

“move/moving” being invalid because they are indefinite, lack sufficient written description, and/or are not enabled, also fail because Defendant has failed to present any argument that meets the clear and convincing standard, in light of ample intrinsic evidence to the contrary.

#### F. “Control the Magnetic Field”

Defendant oversimplifies the requirements of Claim 1 of the ’490 Patent, arguing that the “objective” of Claim 1 is to “increase[] the blood flow of a cortex of the brain or decrease[] the blood flow of a lower region of the brain.” Dkt. 34 at \*17. However, Claim 1 is system claim for a “magnetic field generator” which utilizes a “subject data value”, i.e. an intrinsic frequency, Q-Factor, coherence value, or EEG phase, and configures a magnetic field to “move” the intrinsic frequency, Q-Factor, coherence value, or EEG phase in the manner dictated in the claim. *See* Dkt. 029-04, ’490 Patent at 85:1-39; Bikson Dec. ¶ 152. This magnetic field *also* “increases the blood flow of a cortex of the brain or decreases the blood flow of a lower region of the brain.” *Id.* 86:1-3. Thus, there are two “objectives” of Claim 1 of the ’490 Patent: (1) to move the intrinsic frequency, etc... and (2) to increase or decrease blood flow in the specific regions of the brain. Any argument to the contrary ignores the “move” language of the claim.

To the extent Defendant’s arguments as to indefiniteness and/or invalidity of the claim term “control the magnetic field” are again based upon the *how*, *when*, and *what* questions answered in the previous section, Wave incorporates its response to the “move/moving” terms above<sup>15</sup>; in particular how the ’490 Patent discloses controlling a magnetic field to move a patient’s intrinsic frequency, etc... towards a target or goal.<sup>16</sup> *See supra* at \*19-22.

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<sup>15</sup> *See also* additional supporting intrinsic evidence. *See* Bikson Dec. ¶¶ 154-68.

<sup>16</sup> These arguments also render Defendant’s arguments regarding “prescribed treatment” and “biological feedback sensor” nonsensical. A POSITA would understand that the “prescribed treatment” mentioned in an example of the ’490 Patent would consist of the treatment protocol for the patient to move the patient’s intrinsic frequency, etc... towards the goal or target intrinsic frequency, etc... using the magnetic field and manipulating the magnetic field using the four parameters. *See* Bikson Dec. ¶ 173. A POSITA would also understand that a “biological feedback

Defendant's arguments regarding use of the "control" term in the specification are equally misplaced. Dkt. 34 at \*18-19. Defendant admits that "control" is repeatedly disclosed in the specification to discuss controlling frequency of a magnetic field, one of the four factors discussed above. *Id.* at \*19. And Defendant admits that the word "control" is used elsewhere to discuss controlling "speed" of the device applying the magnetic field, etc.... *Id.* Since the '490 Patent contains disclosures regarding controlling and manipulating the magnetic field as discussed above, and since the term "control" is used throughout the specification to discuss such measures<sup>17</sup>, Defendant's arguments that the "control" disclosures are vague or insufficient is unsupported.

Likewise, a POSITA would understand that when applying a magnetic field, i.e. TMS treatment to a subject, blood flow in the cortex of a subject would likely increase as the movement occurs. *See* Bikson Dec. ¶ 201. This is, at least partly, because the TMS treatment is mostly applied to the cortex of a patient's brain, rather than a "lower region of the brain". *Id.* ¶ 179. Similarly, a POSITA would also understand that, at times, when applying the magnetic field (primarily to the cortex of the brain), blood flow in the "lower region of the brain", i.e. the sub-cortical region of the brain<sup>18</sup>, would decrease. *Id.* ¶ 201. Both of these results, i.e. the increase or decrease of blood flow are well-known results in TMS treatment that a POSITA would understand. *Id.*

Defendant asserts that Claim 1 of the '490 Patent is not enabled because "the claim language literally requires experimentation" and that a POSITA "would necessarily have to experiment significantly" to practice Claim 1 of the '490 Patent. *See* Dkt. 34 at \*17-18. A claim is

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<sup>17</sup> "sensor" could aid in this process, but is not necessary to achieve the process. *Id.* ¶ 174.

<sup>18</sup> To the extent there remains any confusion, "control" is used throughout the specification of the '490 Patent regarding controlling the magnetic field through the parameters available and known to a POSITA. *See* Bikson Dec. ¶¶ 155-68; Dkt. 029-04, '490 Patent at Figures 4, 7-9, 24-25, 21:61-67, 41:64-42:4, 42:10-17, 42:22-30, 42:31-38, 45:65-46:6, 46:7-23, 52:42-47, 52:53-56, 55:62-56:4, 9- 16, 65:53-58, 66:23-27, 67:6-14, 76:65-77:67, 83:49-84:8.

<sup>19</sup> To the extent Defendant's argument focuses on the "lower region of the brain" language, Wave incorporates its response regarding "lower region of the brain". *See infra* at \*25-27.

“not enabled” only when a POSITA “could not practice” the claim’s “full scope without undue experimentation”. *Wyeth and Cordis*, 720 F.3d at 1384. Defendant never addresses this standard, i.e. “undue experimentation” for enablement, let alone provides any evidence supporting that any experimentation needed to practice Claim 1 of the ’490 Patent is, in fact, “undue”. In any case, as explained above in regards to manipulating the “magnetic field” to move an intrinsic frequency, etc..., a POSITA would understand how to use the four parameters to manipulate and control a magnetic field without “undue” experimentation. *See supra* at \*19-20; Bikson Dec. ¶¶ 169-72.<sup>19</sup>

**G. “A frequency that decreases blood flow in a lower region of the brain of the subject”/”The magnetic Field . . . decreases the blood flow of a lower region of the brain”**

Defendant next argues that “decreases blood flow” and “lower region of the brain” are both phrases that are invalid and indefinite.<sup>20</sup> Dkt. 34 at \*20-21.<sup>21</sup> In essence, Defendant argues that “lower region of the brain” is vague and unclear because it could refer to multiple regions of the brain, such as the hindbrain, basal ganglia, and limbic system, among others. *Id.* As explained by Dr. Bikson, the phrase “lower region of the brain” is easily understood by a POSITA as the subcortical regions of the brain. Bikson Dec. ¶¶ 192, 197. This is particularly apparent when the disputed phrase “lower region of the brain” is read in context of the claims as required: “wherein the magnetic field increases the blood flow of a cortex of the brain or decreases the blood flow of a lower region of a brain”. Dkt. 029-04, ’490 Patent, Claim 1, 86:1-3. Compare Dkt. 029-05, ’737 Patent, Claim 1, 80:7-8 (“wherein the pre-selected intrinsic frequency is a frequency that increases blood flow in the cortex of the subject”) with ’737 Patent, Claim 2, 80:18-20 (“wherein the pre-

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<sup>19</sup> Defendant also argues that the ’490 Patent is invalid for failing to disclose the best mode. *See* Dkt. 34 at \*20. While Wave disagrees that it failed to describe the best mode, failure to describe the “best mode” is no longer a valid ground for invalidating a patent. *See supra* at \*6, n. 3.

<sup>20</sup> Defendant also argues that this term is invalid for the same reasons as “move”/”moving”. As such, Wave incorporates its argument regarding “move”/”moving” herein. *See supra* at \*19-23.

<sup>21</sup> Wave notes that “decreases blood flow” and “lower region of the brain” are not used in Claim 1 of the ’737 Patent.

selected intrinsic frequency is a frequency that decreases blood flow in a lower region of the brain of the subject"); *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1374 (Fed. Cir. 1999); Bikson Dec. ¶ 184. The "lower region" is the region below the cortical region of the brain that is specifically referenced in the corresponding claim language. Thus, this claim element is well understood by a POSITA and not indefinite.

Defendant's argument regarding "decreases blood flow" is equally flawed. Defendant first argues that "in the field of neuroscience, a POSITA would never claim that blood flow in the brain uniformly or binarily increases or decreases". Dkt. 34 at \*21. However, the claims do not require that the blood flow increases or decreases "uniformly". Instead, the claims provide that, collectively across the cortex blood flow increases or collectively across the lower region of the brain blood flow decreases. As explained by Dr. Bikson, this collective movement is understood by a POSITA, and would likely be understood by Dr. Dempsey if he were, in fact, a POSITA. Bikson Dec. ¶¶ 200-1. Moreover, *if* Defendant's argument was correct, then it would apply equally to the other portion of the claim element, i.e. the "increases blood flow in the cortex of the subject". However, Defendant does not claim that this portion of the claim element is indefinite or invalid.

The intrinsic and extrinsic evidence supports such an understanding by a POSITA:

- "Increased neuronal activity in a region of the brain is associated with an increase in blood flow". '737 Patent 30:62-63; '490 Patent, 32:23-24; Bikson Dec. ¶ 179.
- "Using the therapy, activation of the cortex occurs, especially in the frontal region, whereas deactivation occurs in the rear and lower regions of the brain." '737 Patent, 77:46-48. '490 Patent, 83:19-21; Bikson Dec. ¶ 180. *See also* Bikson Dec. ¶¶ 177-96.

Tellingly, Defendant does not cite any portion of the specification to support its argument and, instead, relies entirely on extrinsic evidence from its unqualified expert. In any case, because the "lower region of the brain" is understood by a POSITA as explained above, there is no need to identify the specific portion of the "lower region of the brain" where the decreased blood flow may

or may not occur. *Id.* ¶¶ 198-99. The POSITA would understand that the collective decrease in blood flow occurs across the “lower region of the brain”. This claim term is thus, not indefinite.

#### **H. “adjusting [a setting].../[frequency]/[output]**

Defendant primarily relies on and incorporates its arguments regarding “control the magnetic field” into this section. Dkt. 34 at \*21. As such, Wave also incorporates by reference its arguments regarding “move”/“moving” and “control the magnetic field” (as these terms themselves overlap) by reference in response to this section.<sup>22</sup> *See supra* at \*19-25. For the reasons outlined above, the asserted claims of the ’408 and ’737 Patents are not indefinite.

Additionally, in the last paragraph of this section, Defendant makes an unsupported and confusing argument that the “aspect that is missing from the disclosure” is the “ability to achieve an objective by adjusting either ‘a setting’ or ‘the output’ of a magnetic field”. Dkt. 34 at \*22. For the reasons detailed above, the subject specifications contain ample disclosure explaining how to adjust a magnetic field, including the settings, strength, and other attributes, of the field itself. Thus, Defendant’s unsupported argument must fail.

#### **I. “One synchronized magnetic field”**

Defendant again attempts to create an issue for claim construction by improperly reading and objecting to only a portion of a claim element. Specifically, Defendant claims that “one synchronized magnetic field” as used is “non-sensical” and “impossibl[e]”. Dkt. 34 at \*22. However, a mere reading of the entire claim element undermines Defendant’s argument.

First, Defendant ignores the preceding two words of the claim element: “*at least* one synchronized magnetic field”. Dkt. 029-03, ’408 Patent, 66:38-39 (Claim 1), 67:51 (Claim 12)

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<sup>22</sup> *See also* additional supporting intrinsic evidence supporting that this term (and the other related terms) are not indefinite: ’737 Patent 14:42-15:20; ’408 Patent 15:24-33; ’737 Patent 20:4-14; 408 Patent 47:6-48:23; ’737 Patent, 59:25-60:44; ’408 Patent 61:47-62:12; Bikson Dec. ¶¶ 204-16.

(emphasis added). This “at least” language is important and contemplates that more than one synchronized magnetic field may be used. Bikson Dec. ¶¶ 218-20, 225.

Second, Defendant also ignores the remaining context of the claim element. In full, the claim element states:

“move a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value using the magnetic field wherein if the coherence value is higher than the target coherence value, applying at least **two asynchronous magnetic fields** close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least **one synchronized magnetic field** close to the head of the subject”.

Dkt. 029-03, '408 Patent, 66:31-39 (Claim 1). *See also id.* 67:44-52 (similar for Claim 12) (emphasis added). The full claim explains that if a POSITA is trying to decrease a coherence value to reach a target coherence value, the POSITA should apply at least two asynchronous magnetic fields. To be synchronized, there must be at least two magnetic fields used. Bikson Dec. ¶ 221-23. However, if the POSITA is trying to increase a coherence value to reach a target coherence value, the POSITA should apply one or more synchronized magnetic fields. *Id.* Since the fields must be synchronized if there is more than one magnetic field used, the inclusion of the word one recognizes that only one magnetic field may be used for the treatment, but also covers that if more than one field is used, the fields must be synchronized. *Id.* *See also* '408 Patent 49:27-35 (explaining how two synchronized magnets would work during treatment). There is nothing nonsensical or impossible about the language when properly read in the context of the claims.

#### J. “Close to the Head”

No.	Claim Term/Phrase	Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
24	Close to the head '490 Patent, Claim 1 '408 Patent, Claims 1-2 '737 Patent, Claims 1-2	Plain and ordinary meaning, namely wherein the head is not outside the magnetic field.	“Near the head, but not on the head.”

Defendant again attempts to manufacture an issue where none exists. This time regarding the placement of the magnetic field and machines utilizing the magnetic field. For exemplary purposes, Claim 1 of the '408 Patent states “applying said magnetic field close to the head of the subject”. Dkt. 029-03, '408 Patent 66:49-50. Bikson Dec. ¶¶ 229-39. “Close to the head” is used extensively throughout the specifications of the '490, '408, and '737 Patents. *See* Dkt. 29-1 at \*21-26 (listing approximately 15 pages worth of intrinsic references to “close to the head”); Bikson Dec. ¶¶ 240-42. Virtually all of these references uses “close to the head” in the context of ensuring the magnetic field is close enough to head for the TMS protocol to work, i.e. within the zone of the magnetic field. *Id.* ¶¶ 228-42.

Defendant’s proposed construction, instead, improperly focuses on the location of the magnets, rather than the claimed magnetic field and its function within the context of the claim, i.e. to affect treatment using magnets. Regardless, Defendant should understand that the magnets used to create the magnetic field (whether permanent magnets or electromagnets) are typically encased on a protective sleeve or device. *See id.* ¶ 243. For example, the MagVenture device that Defendant requires its customers to use, encases the electromagnet in a case. *Id.*; Dkt. 30-8 at \*14. Because the magnet is enclosed within the case, the magnet can never be placed directly on the head and is always, at best, near it. Bikson Dec. ¶ 243. Defendant’s proposed construction fails to either incorporate the actual structure of the subject device or understand this distinction.

In any case, claim construction is intended to be utilized to construe claims that may have a dispositive effect on the underlying litigation. Since Defendant requires its customers to use its product in conjunction with a device that will never allow the electromagnet to be placed directly on the head of the subject, construction of this term is neither necessary nor helpful to the jury. *See Eon CorpIP Holdings LLC v. Aruba Networks Inc.*, 62 F.Supp.3d 942, 953 (N.D. Cal. 2014).

## K. “Second” and “third” intrinsic frequency

No.	Claim Term/Phrase	Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
25	“Second” and “Third” intrinsic frequency ’490 Patent, Claim 1	Plain and ordinary meaning, namely a second intrinsic frequency and a third intrinsic frequency, wherein the second and third intrinsic frequencies are measured from different sites in the brain, wherein the first intrinsic frequency may be measured from the same or a different site of the brain as the second and/or third intrinsic frequencies.	“Second intrinsic frequency, (which is not the same as the first).” “Third intrinsic frequency (which is not the same as the first or second).”

Lastly, Defendant claims that the “first”, “second”, and “third” intrinsic frequencies listed in the ’490 Patent “cannot be the same ‘intrinsic frequencies’”. Dkt. 34 at \*25. Again, Defendant oversimplifies the claims to suit its own aims. Tellingly, Defendant does not provide the Court with the context for each of these intrinsic frequencies as listed in the claims as shown below:

“a non-transitory computer readable medium containing a Subject data value comprising i) a **first intrinsic frequency** of a brain of the subject within a specified EEG band . . . iii) a coherence value of a **second intrinsic frequency** and a **third intrinsic frequency**, wherein the second and third intrinsic frequencies are from two different sites in the brain of the subject within the specified EEG band . . . ”

The claim language contemplates different measurements and the locations of these measurements, not that the frequencies themselves, i.e. the numerical values of the frequencies, must be different. Bikson Dec. ¶¶ 248-52. However, Defendant’s proposed construction implies just that, i.e. that the numerical values of the frequencies must be different.

Importantly, Defendant provides no intrinsic or extrinsic support for its argument. Nor can it. The specification focuses on the location of the intrinsic frequencies and does not require that the numerical value of the frequencies be different. *See* ’490 Patent 5:12-19, 11:9-13, ’490 Patent 20:36-48, for example. Wave’s plain and ordinary meaning of the terms reflects this. And a POSITA would understand that the use of “first”, “second”, and “third” reflects that different measurements were taken, not that they need be taken at specific locations. *See* Bikson Dec. ¶ 252.

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Respectfully submitted,

/s/ J. Rick Taché

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that counsel of record who are deemed to have consented to electronic services are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a) on May 31, 2024.

/s/ J. Rick Taché

J. Rick Taché